

Via email to www.cms.hhs.gov/regulations/ecomments and dshannon2@cms.hhs.gov

September 24, 2004

Mark McClellan, M.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1429-P
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, District of Columbia 21244-1850

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for
Calendar Year 2005; Proposed Rule
*Therapy – Incident To
Therapy Standards and Requirements
Section 302
Section 611*

Dear Doctor McClellan:

The American Occupational Therapy Association (AOTA) represents approximately 40,000 occupational therapy professionals, many of whom provide outpatient services to Medicare beneficiaries. We appreciate the opportunity to comment on the proposed changes affecting payment and policies under the Physician Fee Schedule. This proposed rule was published in the *Federal Register* on August 5, 2004 (69 Fed. Reg. 47488). AOTA's detailed comments follow.

First, however, we must again request that the Centers for Medicare and Medicaid Services (CMS), when discussing the Physical Medicine and Rehabilitation (PM&R) codes (CPT 97000 series), refer to them as "PM&R" or "Rehabilitation" codes, not as "Physical Therapy" (e.g. 69 Fed. Reg. 47492). It is erroneous to refer to these codes as belonging to a specific profession, when they are equally valid for multiple occupations including occupational therapy.

I. Outpatient Therapy Performed “Incident To” Physicians’ Services

In the proposed rule, CMS proposes to revise 42 C.F.R. §§ 410.26, 410.59, 410.60 and 410.62 to reflect that occupational therapy services provided incident to a physician’s professional services may only be furnished by individuals who meet the existing qualifications for occupational therapists and appropriately supervised occupational therapy assistants as set forth in 42 C.F.R. § 484.4. AOTA unequivocally supports this proposal and urges CMS to finalize it.

For a number of years, AOTA has urged CMS to change this regulation to assure that Medicare beneficiaries can expect occupational therapy services to be delivered by qualified personnel under all Medicare benefits.

This change is long overdue. Not only is it consistent with the Medicare statute, but also it will better achieve consistency in the Medicare personnel requirements under all benefits. More importantly, it should assure that beneficiaries receive authentic and higher quality services. Recently, research conducted by CMS regarding the impending financial limitations on outpatient therapy services have emphasized the need to define the qualifications of those providing therapy services to help assure that precious therapy dollars are spent on bona fide therapy. AOTA is concerned that therapy services in physicians' offices may have been performed by less skilled personnel (e.g., aides, technicians, or athletic trainers) and agrees with CMS that such practices are inconsistent with the law.

II. Personnel Qualifications for Outpatient Occupational Therapy

AOTA urges CMS to expediently update the antiquated qualification standards for occupational therapists and occupational therapy assistants and to incorporate these standards into the regulations at 42 C.F.R. § 410 et. seq. Since these qualifications are set forth in the home health conditions of participation regulations, updating these rules has been long delayed. In addition, it makes no sense that the therapy personnel qualifications that apply to all Medicare Part B settings only reside in the home health regulations. It takes at least an hour of flipping through the Code of Federal Regulations to trace the connection between the coverage criteria for occupational therapy in § 410.59 and the personnel standards in § 484.4, and then it requires a law degree to be confident that those personnel regulations do apply to Medicare Part B services. AOTA suggests that CMS simplify this tangled web of regulations by placing the personnel qualifications for covered services in close proximity to the regulations that outline the scope of the benefits available under Medicare Part B. AOTA recommends that CMS adopt the following updated standards for the qualification of occupational therapists and occupational therapy assistant:

A qualified occupational therapist is a person who is licensed or otherwise regulated as an occupational therapist by the State in which he or she is practicing. In addition, the occupational therapist has graduated from an occupational therapy program accredited by the American Occupational Therapy Association's Accreditation Council for Occupational Therapy Education (ACOTE) and is eligible for a national entry-level certification examination recognized by the American Occupational Therapy Association.

A qualified occupational therapy assistant is a person who is licensed or otherwise regulated (if applicable) to assist in the practice of occupational therapy by the State in which he or she is practicing and who shall work under the supervision of an occupational therapist. In addition, the occupational therapy assistant has graduated from an occupational therapy assistant program accredited by the American Occupational Therapy Association's Accreditation Council for Occupational Therapy Education (ACOTE) and is eligible for a national entry-level certification examination recognized by the American Occupational Therapy Association.

III. Qualification Standards and Supervision Requirements in Occupational Therapy Private Practice Settings

In this rule, CMS proposes to change the occupational therapy assistant (OTA) supervision requirements for the private practice setting from "personal" supervision to "direct" supervision. AOTA unequivocally supports this proposal and urges CMS to finalize this change.

Since 1998, when the current requirement was promulgated, AOTA has pointed out to CMS that the current supervision standard for OTAs in occupational therapy private practices (OTPPs) inappropriately exceeds the standard Medicare requires in every other setting in which OTAs work. AOTA applauds CMS for proposing a clinically correct and workable supervision requirement for OTAs who work in OTPPs that is consistent with professional practice and standards. CMS also should be commended for proposing this change because it promotes consistency in Medicare's policies regarding supervision of OTAs in all settings. AOTA also agrees with the proposal to restore the qualifications of OTAs at 42 § 410.59, which had been inadvertently removed.

IV. Section 302- Clinical Conditions for Coverage of Durable Medical Equipment

CMS has proposed expanding the requirements for clinical conditions of coverage to the medical supplies, appliances and devices commonly referred to as prosthetics, orthotics and supplies (POS). CMS has asserted that these items require the same level of medical intervention and skill as durable medical equipment (DME) and that it is appropriate for beneficiaries requiring DMEPOS to be under the care of a physician and for DMEPOS orders to occur in the context of routine clinical care.

Occupational therapists provide orthotics and supplies to meet patients' needs. They evaluate, recommend, design, measure, fabricate, fit, and train patients in the use of orthotics and train in the use of prosthetics. The Medicare coverage rules permit occupational therapists to fabricate and furnish orthotics, prosthetics, and supplies to beneficiaries in a variety of settings, including independently as Medicare enrolled OTPPs (occupational therapists in private practice), in physician offices, or as employees in a facility. In these instances, the occupational therapist or provider (where required) additionally enrolls in the Medicare program as a DMEPOS supplier. In fact, § 427 of the Benefits Improvement and Protection Act of 2000 (BIPA) specifically includes qualified occupational therapists as "qualified practitioners" who are able to furnish prosthetics and custom fabricated orthotics. As with all covered occupational therapy services, occupational therapists provide these items to beneficiaries under an occupational therapy plan of care that is approved by a physician. Consequently, the beneficiaries who receive DMEPOS from occupational therapists are already under the care of a physician, and the provision of these items already occurs in the context of routine clinical care.

AOTA agrees with CMS that it is essential to ensure that POS are provided in the context of clinical care in order to assure quality and reduce waste. There have been significant fraudulent and abusive practices alleged in the orthotics and prosthetics industry, which has been able to directly supply beneficiaries with POS sans medically appropriate clinical care. Far too often our members treat patients whose medical conditions previously were exacerbated due to a supplier furnishing an ill-fitting or inappropriate orthotics or other items of DMEPOS. Requiring physician involvement in DMEPOS can only improve the quality provided by this otherwise largely unregulated industry. The regulations at 42 C.F.R. §§ 410.59, 410.61 already require extensive physician involvement in occupational therapy care, through the certification and recertification of the plan of care. These regulatory requirements safeguard against occupational therapists furnishing DMEPOS or other interventions that are inconsistent with good clinical care. It would be duplicative, unduly burdensome and administratively confusing to additionally require a face-to-face physician examination of beneficiaries who obtain DMEPOS under an occupational therapy plan of care. Consequently, AOTA urges CMS to exempt DMEPOS furnished under an occupational therapy plan of care from the proposed revisions to § 410.36 and § 410.38 related to the face-to face examination by a physician.

V. Section 611 – Initial Preventative Physical Examination

AOTA supports CMS' proposed definition of the new initial preventative physical examination benefit. In particular, AOTA agrees that a review of the beneficiary's functional ability and level of safety is a crucial component of quality care that must be covered. CMS proposes to define this benefit as including, "at a minimum, a review of ...activities of daily living, falls risk and home safety." 69 Fed. Reg. at 47515. These factors are key indicators of health and independence and fit squarely within the domain of occupational therapy. In fact, scientific research published in the Journal of the American Medical Association (JAMA) has shown the positive effects of preventative occupational therapy in reducing rates of decline and incidence of need for expensive acute or long-term care. See *Occupational therapy for independent-living older adults: A randomized controlled trial.* JAMA, Vol. 278, No. 16, p. 1321-1326. 1999. We agree with CMS' decision to not define the term, "appropriate screening instrument" because the physician will want to use the test of his choice. We would strongly recommend that CMS includes in the guidelines for the initial preventative physical examination information that informs physicians' referrals of the beneficiary to an occupational therapist when a more extensive evaluation of activities of daily living, falls risk, and home safety is warranted and also when the initial screening indicates deficits in these areas in which occupational therapy intervention would be medically appropriate.

The AOTA requests that due consideration be given to these comments. Thank you, again, for the opportunity to comment on this Final Rule. We look forward to a continuing dialogue with CMS on these issues as they apply to occupational therapy.

Sincerely,

Leslie Stein Lloyd, Esq.
Regulatory Counsel